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10/068,292	02/06/2002	Toshikazu Hirota	789 076	9651

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EXAMINER	
LAM, ANN Y	
ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/068,292	Applicant(s) HIROTA ET AL.	
	Examiner Ann Y. Lam	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 33-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/13/02,6/4/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The foreign patents JP 11-187900, JP 11-99000, JP 2000-157272A, JP P2000-295990A, and JP P2000-505281 listed in the information disclosure statements filed June 13, 2002 and June 4, 2002 are not considered since there are no English translations of those patents. The foreign patents JP 10-15857 and JP 6-40030A have been considered only as to the abstracts that were translated into English.

Election/Restrictions

Applicant's election with traverse of Group II (claims 7-32) in the reply filed on October 21, 2004 is acknowledged. The traversal is on the ground(s) that a thorough and complete search for the subject matter of the elected claims would necessarily encompass a thorough and complete search for subject matter of the non-elected claims, and thus a search and examination of all the claims could be made without serious burden to examiner. This is not found persuasive because the subject matter of the non-elected claims include limitations that are not in the elected claims and would require separate search and consideration, resulting in a serious burden to examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6 and 33-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague. The claim is incomplete. The claimed method is for producing a biochip but the only method step recited in the body of the claim is a "supplying" step. The body of the claim does not recite sufficient steps to form a biochip.

Claims 7-32 are vague and confusing in reciting the term "sample". The art accepted definition of "sample" is a solution that contains an unknown/analyte that is to be detected or quantitated. The method of claims 7-32 is for production of a biochip. Using a "sample" solution containing an analyte to make a biochip doesn't make sense.

In claim 7, line 4, what "types" of samples are being referred to?

Claim 7, last 2 lines, recite "a solution sample containing no capture". What is being claimed (water, buffer, saline)?

Claims 13 and 14 are vague since they recite that the sample containing the capture is supplied before or after the immobilization solution or immobilization-

reinforcing solution is supplied, which contradicts claim 11, from which claims 13 and 14 depend, because claim 11 recites mixing the immobilization solution or immobilization-reinforcing solution with the solution sample containing the capture, which implies that the solutions are applied simultaneously.

Claims 31 and 32 are vague since claim 31, line 5 and claim 32, line 5, recite "solution sample containing no capture" is a repetition of line 3 in the claims. (It appears that it should read –solution sample containing capture--, as is described in the specification.)

Regarding claims 21, line 3, and claim 25, line 3, and claim 29, lines 4 and 7, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-9, 11-19, 21-23, 25-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Okamoto et al., 6,476,215.

As to claim 7, Okamoto et al. discloses a method for producing a biochip comprising the step of supplying a solution sample containing capture (i.e., DNA probes in col. 28, line 4, and lines 23-29; and col. 24, line 61- 5) and a solution sample containing no capture (i.e., silane compound in col. 27, lines 40-54) separately from each other to produce the biochip (col. 27, lines 46-47, and col. 28, lines 27-29.)

As to claim 8, the sample containing capture is supplied with an ink-jet system (col. 28, lines 27-29, and col. 24, line 61).

As to claim 9, the sample containing no capture is supplied in accordance with an ink-jet system (col. 27, lines 46-55, and col. 24, line 61.)

As to claim 11, the solution sample containing no capture (e.g., amino or epoxy group in col. 13, lines 38-39) is an immobilization solution for immobilizing said captures onto said base plate or an immobilization-reinforcing solution for reinforcing immobilization of said captures onto said base plate (col. 5, lines 40-41, and col. 6, lines 58-61).

As to claim 12, the immobilization solution or the immobilization-reinforcing solution is advanced by mixing the immobilization solution or immobilization-reinforcing solution with the solution sample containing the capture (col. 5, lines 45-48, and col. 16, lines 50-51, and col. 8, lines 15-16.)

As to claim 13, the solution sample containing said capture is supplied onto said base plate, and then said immobilization-reinforcing solution (i.e., ethanol amine, col., 13, line 27) is supplied to parts to which said sample has been supplied (col. 13, lines 25-27.)

As to claim 14, the immobilization solution or immobilization-reinforcing solution (i.e., the silane coupling agent, col. 28, line 40) is supplied onto said base plate, and then said solution sample containing said capture is supplied to parts to which said immobilization solution or immobilization-reinforcing solution has been supplied (col. 28, lines 25-27.)

As to claim 15, the immobilization solution or immobilization-reinforcing solution (i.e., the thiol group, col. 5, line 57) and the solution sample containing said capture (i.e., the nucleic acid probe, col. 5, line 56) are supplied substantially simultaneously onto said base plate (col. 5, lines 56-60.)

As to claim 16, the captures are nucleic acids (col. 5, line 56).

As to claim 17, the nucleic acid is DNA (col. 16, line 50.)

As to claim 18, the captures are proteins (col. 10, line 55.)

As to claim 19, the protein is antibody (col. 10, line 55.)

As to claim 21, the immobilization solution is a silane coupling agent (col. 27, line 40.)

As to claim 22, the immobilization solution includes a chemical substance for chemically modifying a base plate surface, and a functional group introduced into said base plate surface and a functional group introduced by modifying said capture are subjected to a chemical reaction to immobilize said capture onto said base plate by means of covalent bond (col. 7, lines 1-3.)

As to claim 23, the chemical reaction is a reaction of an amino group and epoxy group (col. 6, lines 60-62.)

As to claim 25, the immobilization solution is a solution containing hydrophobic group (i.e., epoxy group, col. 13, lines 24-26.)

As to Claims 26-29, since the immobilization-reinforcing solution was recited in the alternative (see claim 11), these claims are anticipated by the disclosure of the immobilization solution (i.e., epoxy group, col. 6, line 60.)

As to claim 30, the method further comprises preparing a jig (125, see col. 11, line 25) to which a plurality of said base plates (exposed surfaces of 103, see fig. 5B) are set, and the solution sample containing said capture and the solution sample containing no capture are supplied in a state in which said base plates are fixed on said jig.

As to claim 31, Examiner notes that since claim 31 is vague as described in the 112 rejection above, for purposes of examination Examiner will interpret claim 31, line 5, as if Applicant intended to mean –solution sample containing capture--. Okamoto et al. discloses an area in which said solution sample containing no capture is supplied is substantially the same as an area to which said solution sample containing capture is supplied, or an area which includes said area to which said solution sample containing said capture is supplied (col. 7, lines 40-54), said area having a substantially circular shape (col. 5, line 23.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto et al., 6,476,215.

(Examiner notes that since claim 32 is vague as described in the 112 rejection above, for purposes of examination Examiner will interpret claim 32, line 5, as if Applicant intended to mean –solution sample containing capture--.)

Okamoto et al. discloses the invention substantially as claimed, except for the area in which the solution sample containing no capture is supplied onto said base plate, has a size which includes two or more areas to each of which said solution sample containing capture is supplied.

However Okamoto et al. discloses that areas with maleimido groups (equivalent to the claimed sample containing no capture) may be larger than the areas with nucleic acid probes (col. 8, lines 12-13). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the areas with maleimido groups with a size at least twice as large as the areas with nucleic acid probes because this is an optimum or workable range and it has been held that where the general conditions of a claim are disclosed in the prior art, as is the case at hand, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*,105 USPQ 233..

2. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto et al., 6,476,215, in view of Robinson et al., 5,856,203.

Okamoto et al. discloses the invention as claimed (see above). More specifically, Okamoto et al. teaches that the solution sample containing no capture is supplied with ink jet or other types of printing (col. 15, lies 29-31.) However Okamoto et al. does not teach that the solution sample containing no capture is supplied with screen printing system.

Robinson et al. teaches a method of manufacturing an assay device including the step of providing reagents using ink-jet printing or screen printing (col. 5, lines 8-11.) Robinson et al. teaches that ink-jet printing and screen printing are conventional printing methods that can be used alternatively (col. 5, lines 8-11.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use screen printing as an alternative to the ink jet printing as taught by Robinson et al. in the Okamoto et al. method of supplying the solution sample containing no capture onto the base plate because Robinson et al. teaches that screen printing is a conventional alternative to ink jet printing for supplying reagents to a solid support.

3. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto et al., 6,476,215, in view of Hammond et al., 6,255,051.

Okamoto et al. discloses the invention substantially as claimed. More specifically, Okamoto et al. discloses use of functional groups introduced into the solid

support and into the probe to form covalent bonds to more firmly fix the probe to the solid support (col. 7, lines 1-4.) However Okamoto et al. does not teach the use of ionic bonds to fix the probe to the solid support.

Hammond et al. teaches that, in addition to functional groups providing covalent bonds between nucleic acids and a solid support, ionic interactions can also facilitate immobilization of nucleic acids onto a solid support (col. 18, lines 8-14 and lines 19-20.) Hammond et al. teaches that the binding can be direct as between the nucleic acid and solid support, or indirect such that an intermediate molecule lies between the nucleic acid and the solid support (col. 18, lines 21-23.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for ionic bonds between the nucleic acids and the solid support as taught by Hammond et al. in the Okamoto et al. device because Hammond et al. teaches that providing for ionic bonds is an alternative to providing for covalent bonds to immobilize nucleic acids onto a solid support.

4. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto et al., 6,476,215, in view of Dattagupta, 4,950,588.

Okamoto et al. discloses the invention substantially as claimed. More specifically, Okamoto et al. discloses use of functional groups introduced into the solid support and into the probe to form covalent bonds to more firmly fix the probe to the solid support (col. 7, lines 1-4.) However Okamoto et al. does not teach that the immobilization solution includes avidin.

Dattagupta teaches that, in addition to functional groups providing covalent bonds between nucleic acids and a solid support, the bonding between the nucleic acid and solid support can be through use of avidin as a linker (col. 18, lines 1-12, and col. 19, line 4.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use avidin as a linker between the nucleic acids and the solid support as taught by Dattagupta in the Okamoto et al. device because Dattagupta teaches that use of avidin is an alternative to providing for covalent bonds to immobilize nucleic acids onto a solid support.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

Christopher L. Chin

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1/21/05